

Subpart C—Recordkeeping Requirements

§ 721.100 Applicability.

This subpart C identifies certain additional recordkeeping requirements applicable to manufacturers, importers, and processors of substances identified in subpart E of this part for each specific substance. The provisions of this subpart C apply only when referenced in subpart E of this part for a substance and significant new use identified in that subpart E. If the provisions in this subpart C conflict with general provisions of subpart A of this part, the provisions of this subpart C shall apply.

[54 FR 31313, July 27, 1989]

§ 721.125 Recordkeeping requirements.

At the time EPA adds a substance to subpart E of this part, EPA will specify appropriate recordkeeping requirements which correspond to the significant new use designations for the substance selected from subpart B of this part. Each manufacturer, importer, and processor of the substance shall maintain the records for 5 years from the date of their creation. In addition to the records specified in § 721.40, the records whose maintenance this section requires may include the following:

- (a) Records documenting the manufacture and importation volume of the substance and the corresponding dates of manufacture and import.
- (b) Records documenting volumes of the substance purchased in the United States by processors of the substance, names and addresses of suppliers, and corresponding dates of purchase.
- (c) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture, importation, or processing to whom the manufacturer, importer, or processor directly sells or transfers the substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date.
- (d) Records documenting establishment and implementation of a program for the use of any applicable personal

protective equipment required under § 721.63.

(e) Records documenting the determinations required by § 721.63(a)(3) that chemical protective clothing is impervious to the substance.

(f) Records documenting establishment and implementation of the hazard communication program required under § 721.72.

(g) Copies of labels required under § 721.72(b).

(h) Copies of material safety data sheets required under § 721.72(c).

(i) Records documenting compliance with any applicable industrial, commercial, and consumer use limitations under § 721.80.

(j) Records documenting compliance with any applicable disposal requirements under § 721.85, including the method of disposal, location of disposal sites, dates of disposal, and volume of the substance disposed. Where the estimated disposal volume is not known to or reasonably ascertainable by the manufacturer, importer, or processor, that person must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

(k) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitations under § 721.90.

[54 FR 31313, July 27, 1989]

Subpart D—Expedited Process for Issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules

SOURCE: 54 FR 31314, July 27, 1989, unless otherwise noted.

§ 721.160 Notification requirements for new chemical substances subject to section 5(e) orders.

(a) *Selection of substances.* (1) In accordance with the expedited process specified in this section, EPA will issue significant new use notification requirements and other specific requirements for each new chemical substance

that is the subject of a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture and import of the substance, unless EPA determines that significant new use notification requirements are not needed for the substance.

(2) If EPA determines that significant new use notification requirements are not needed for a substance that is subject to a final order issued under section 5(e) of the Act, except for an order that prohibits manufacture or import of the substance, EPA will issue a notice in the FEDERAL REGISTER explaining why the significant new use requirements are not needed.

(b) *Designation of requirements.* (1) The significant new use notification and other specific requirements will be based on and be consistent with the provisions included in the final order issued for the substance under section 5(e) of the Act. EPA may also designate additional activities as significant new uses which will be subject to notification. Designation of additional activities as significant new uses will be done in accordance with the criteria and procedures under § 721.170, or through a separate rulemaking proceeding.

(2) Significant new use requirements and other specific requirements designated under this section will be listed in subpart E of this part. For each substance, subpart E will identify:

- (i) The chemical name.
- (ii) The activities designated as significant new uses.
- (iii) Other specific requirements applicable to the substance, including recordkeeping requirements or any other requirements included in the final section 5(e) order.

(c) *Procedures for issuing significant new use rules.* (1) EPA will issue significant new use rules under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(2) FEDERAL REGISTER documents issued to propose or establish signifi-

cant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by EPA.

(ii) The premanufacture notice number.

(iii) The CAS number, where available and not claimed confidential.

(iv) A summary of EPA's findings under section 5(e)(1)(A) of the Act for the final order issued under section 5(e).

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of subpart A of this part applicable to the specific substance and significant new uses.

(vii) If the FEDERAL REGISTER document establishes a final rule, or notifies the public that a final rule will not be issued after public comment has been received, the document will describe comments received and EPA's response.

(3) *Direct final rulemaking.* (i) When EPA uses the direct final rulemaking procedure to issue a significant new use rule, it will issue a final rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(ii) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days of publication that someone wishes to submit adverse or critical comments, the rule will be effective 60 days from the date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and a proposal will

be published in the proposed rule section of the FEDERAL REGISTER. The proposal will establish a 30-day comment period.

(iii) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(4) *Notice and comment rulemaking.* (i) When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposal in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(ii) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(5) *Interim final rulemaking.* (i) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(A) The significant new use rule will take effect on the date of publication.

(B) Persons will be given 30 days from the date of publication to submit comments.

(ii) Interim final rules issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30-day comment period specified in paragraph (c)(5)(i)(B) of this section and promulgating final significant new use notification re-

quirements and other requirements for the substance.

(d) *Schedule for issuing significant new use rules.* (1) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 180 days of receipt of a valid notice of commencement under § 720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) Unless EPA determines that a significant new use rule should not be issued under this section, EPA will issue a proposed rule, a direct final rule, or an interim final rule within 1 year of October 10, 1989, for any substance for which the valid notice of commencement under § 720.102 of this chapter was received before October 10, 1989.

(3) If EPA receives adverse or critical significant comments following publication of a proposed or interim final rule, EPA will either withdraw the rule or issue a final rule addressing the comments received.

§ 721.170 Notification requirements for selected new chemical substances that have completed premanufacture review.

(a) *Selection of substances.* In accordance with the expedited process specified in this section, EPA may issue significant new use notification and recordkeeping requirements for any new chemical substance for which a premanufacture notice has been submitted under part 720 of this chapter if EPA determines that activities other than those described in the premanufacture notice may result in significant changes in human exposure or environmental release levels and/or that concern exists about the substance's health or environmental effects.

(b) *Concern criteria.* EPA may determine that concern exists about a substance's health or environmental effects if EPA makes any one of the following findings:

(1)(i) The substance may cause carcinogenic effects because the substance:

(A) Has been shown by valid test data to cause carcinogenic effects in humans or in at least one species of laboratory animal.

(B) Has been shown to be a possible carcinogen based on the weight of the evidence in short-term tests indicative of the potential to cause carcinogenic effects.

(C) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by test data to cause carcinogenic effects in humans or in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(D) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause carcinogenic effects under the criteria in paragraphs (b)(1)(i) (A), (B), or (C) of this section.

(ii) No substance may be regulated based on a finding under paragraph (b)(1) of this section unless EPA has also made the finding under § 721.170(c)(2)(ii).

(2) The substance has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal or is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause acutely toxic effects in at least one species of laboratory animal, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(3) The substance may cause serious chronic effects, serious acute effects, or developmentally toxic effects under reasonably anticipated conditions of exposure because the substance:

(i) Has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose

levels that could be of concern under reasonably anticipated conditions of exposure.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another chemical substance that has been shown by valid test data to cause serious chronic effects, serious acute effects, or developmentally toxic effects in humans or in at least one species of laboratory animal at dose levels that could be of concern under reasonably anticipated conditions of exposure, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be metabolized in humans or transformed in the environment to a substance which may have the potential to cause serious chronic effects, serious acute effects, or developmentally toxic effects under the criteria in paragraph (b)(3) (i) and (ii) of this section.

(iv) Has been shown to potentially cause developmentally toxic effects based on the weight of the evidence in short-term tests indicative of the potential to cause developmentally toxic effects.

(4) The substance may cause significant adverse environmental effects under reasonably anticipated conditions of release because the substance:

(i) Has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(ii) Is closely analogous, based on toxicologically relevant similarities in molecular structure and physical properties, to another substance that has been shown by valid test data to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release, provided that if there is more than one such analogue, the greatest weight will be given to the relevant data for the most appropriate analogues.

(iii) Has been determined, based on calculations using the substance's

physical and chemical properties, to be potentially able to cause significant adverse environmental effects at dose levels that could be of concern under reasonably anticipated conditions of release.

(iv) Is known or can reasonably be anticipated, based on valid scientific data or established scientific principles, to be environmentally transformed to a substance which may have the potential to cause significant adverse environmental effects under the criteria in paragraph (b)(4) (i), (ii), and (iii) of this section.

(5) Concern exists about the health or environmental effects of one or more impurities or byproducts of the substance because the impurity or byproduct meets one or more of the criteria in paragraph (b) (1) through (4) of this section and either:

(i) The impurity or byproduct is a new chemical substance and may be present in concentrations that could cause adverse health or environmental effects under reasonably anticipated conditions of exposure or release.

(ii) Reasonably anticipated manufacture, processing, or use activities involving the substance for which a premanufacture notice has been submitted may result in significantly increased human exposure to or environmental release of the impurity or byproduct compared to exposure or release levels resulting from existing activities involving the impurity or byproduct.

(c) *Designation of requirements.* (1) When EPA decides to establish significant new use reporting requirements under this section, EPA may designate as a significant new use any one or more of the activities set forth in subpart B of this part. In addition, EPA may designate specific recordkeeping requirements described under subpart C of this part that are applicable to the substance.

(2) EPA may designate as a significant new use only those activities that (i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are sig-

nificant in relation to the health or environmental concerns identified under paragraph (b) of this section.

(d) *Procedures for issuing significant new use rules.* (1) Significant new use requirements designated under this section will be listed in subpart E of this part. For each substance, subpart E of this part will identify:

(i) The chemical name.

(ii) The activities designated as significant new uses, which may include one or more of the activities described in paragraph (c) of this section.

(iii) Other specific requirements applicable to the substance.

(2) When EPA determines that a substance is a candidate for a significant new use rule under this section, it will notify the person that submitted the premanufacture notice for the substance no later than 7 calendar days before the expiration of the notice review period under §720.75 of this chapter. In providing this notice, EPA will describe the health or environmental concerns identified under paragraph (b) of this section and the activities under consideration for designation as significant new uses. Such notice may be by telephone, but in this event will be confirmed in writing no later than 30 days after completion of the notice review period.

(3) FEDERAL REGISTER documents issued to propose or establish significant new uses under this section will contain the following:

(i) The chemical identity of the substance or, if its specific identity is claimed confidential, an appropriate generic chemical name and an accession number assigned by EPA.

(ii) The premanufacture notice number.

(iii) The CAS number, where available and not claimed confidential.

(iv) A summary of the basis for action under this section.

(v) Designation of the significant new uses subject to, or proposed to be subject to, notification and any other applicable requirements.

(vi) Any modifications of subpart A of this part applicable to the specific substance and significant new uses.

(vii) If the FEDERAL REGISTER document establishes a final rule, or notifies the public that a final rule will not

be issued after public comment has been received, the document will describe comments received and EPA's response.

(4) EPA will issue significant new use rules under this section by one of the following three processes: direct final rulemaking, interim final rulemaking, or notice and comment rulemaking. EPA will use the direct final rulemaking process to issue significant new use rules unless it determines that, in a particular case, one of the other processes is more appropriate.

(i)(A) When EPA uses the direct final rulemaking procedure to issue a significant new use rule it will issue a direct final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance.

(B) The FEDERAL REGISTER document will state that, unless written notice is received by EPA within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the SNUR will be effective 60 days from date of publication. The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days after the date of publication that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER, and EPA will issue a proposed rule in the proposed rule section of the FEDERAL REGISTER. The proposed rule will establish a 30-day comment period.

(C) If EPA, having considered any timely comments submitted in response to the proposal, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(ii)(A) When EPA uses a notice and comment procedure to issue a signifi-

cant new use rule, EPA will issue a proposed rule in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance. Persons will be given 30 days to comment on whether EPA should establish notification requirements for the substance under this part.

(B) If EPA, having considered any timely comments, decides to establish notification requirements under this section, EPA will issue a final rule adding the substance to subpart E of this part and designating the significant new uses subject to notification.

(iii)(A) When EPA uses the interim final rulemaking procedure to issue a significant new use rule, EPA will issue an interim final rule in the final rule section of the FEDERAL REGISTER following its decision to develop a significant new use rule for a specific new chemical substance. The document will state EPA's reasons for using the interim final rulemaking procedure.

(1) The significant new use rule will take effect on the date of publication.

(2) Persons will be given 30 days from the date of publication to submit comments.

(B) An interim final rule issued under this section shall cease to be in effect 180 days after publication unless, within the 180-day period, EPA issues a final rule in the FEDERAL REGISTER responding to any written comments received during the 30-day comment period specified in paragraph (d)(4)(iii)(A)(2) of this section and promulgating final significant new use notification requirements and other requirements for the substance.

(e) *Schedule for issuing significant new use rules.* (1) EPA will issue a proposed rule, an interim final rule, or a direct final rule within 270 days of receipt of the notice of commencement under § 720.102 of this chapter for any substance for which the notice of commencement was received on or after October 10, 1989.

(2) If EPA receives adverse or critical comments within the designated comment period following publication of a proposed rule or an interim final rule, EPA will either withdraw the rule or

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issue a final rule addressing the comments received.

[54 FR 31314, July 27, 1989, as amended at 60 FR 16316, Mar. 29, 1995]

§ 721.185 Limitation or revocation of certain notification requirements.

(a) *Criteria for modification or revocation.* EPA may at any time modify or revoke significant new use notification requirements for a chemical substance which has been added to subpart E of this part using the procedures under § 721.160 or § 721.170. Such action may be taken under this section if EPA makes one of the following determinations, unless other information shows that the requirements should be retained:

(1) Test data or other information obtained by EPA provide a reasonable basis for concluding that activities designated as significant new uses of the substance will not present an unreasonable risk of injury to human health or the environment.

(2) EPA has promulgated a rule under section 4 or 6 of the Act, or EPA or another agency has taken action under another law for the substance that eliminates the need for significant new use notification under section 5(a)(2) of the Act.

(3) EPA has received significant new use notices for some or all of the activities designated as significant new uses of the substance and, after reviewing such notices, concluded that there is no need to require additional notice from persons who propose to engage in identical or similar activities.

(4) EPA has examined new information, or has reexamined the test data or other information or analysis supporting its decision to add the substance to subpart E of this part under § 721.170 and has concluded that the substance does not meet the criteria under § 721.170(b).

(5) For a substance added to subpart E of this part under § 721.160, EPA has examined new information, or has reexamined the test data or other information or analysis supporting its finding under section 5(e)(1)(A)(ii)(I) of the Act, and has concluded that a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable risk of injury to human health or the environ-

ment required under section 5(e)(1)(A) of the Act.

(6) For a substance added to subpart E of this part under § 721.160, certain activities involving the substance have been designated as significant new uses pending the completion of testing, and adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA.

(b) *Procedures for limitation or revocation.* Modification or revocation of significant new use notification requirements for a substance that has been added to subpart E of this part using the procedures described under § 721.160 or § 721.170 may occur either at EPA's initiative or in response to a written request.

(1) Any affected person may request modification or revocation of significant new use notification requirements for a chemical substance that has been added to subpart E of this part using the procedures described in § 721.160 or § 721.170 by submitting a request that is accompanied by information sufficient to support the request. Persons submitting a request to EPA under this part must submit the request to EPA using e-PMN software in the manner set forth in 40 CFR 720.40(a)(2)(i). See 40 CFR 720.40(a)(2)(ii) for information on how to obtain the e-PMN software. Support documents related to these requests must also be submitted to EPA in the manner set forth in 40 CFR 720.40(c).

(2) The Director of the Office of Pollution Prevention and Toxics will consider the request, make a determination whether to initiate rulemaking to modify the requirements, and notify the requester of that determination by certified letter. If the request is denied, the letter will explain why EPA has concluded that the significant new use notification requirements for that substance should remain in effect.

(3) If EPA concludes that significant new use notification requirements for a substance should be limited or revoked, EPA will propose the changes in the FEDERAL REGISTER, briefly describe the

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grounds for the action, and provide interested parties an opportunity to comment.

[54 FR 31314, July 27, 1989, as amended at 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006; 76 FR 30836, May 27, 2011; 78 FR 72827, Dec. 4, 2013]

Subpart E—Significant New Uses for Specific Chemical Substances

§ 721.225 2-Chloro-N-methyl-N-substituted acetamide (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance 2-chloro-N-methyl-N-substituted acetamide (PMN P-84-393) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(3), (b) (concentration set at 1.0 percent), and (c).

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (b)(2), (d), (e) (concentration set at 1.0 percent), (f), (g)(1)(iv), (g)(2)(i), and (g)(2)(v). The provisions of § 721.72(d) requiring employees to be provided with information on the location and availability of a written hazard communication program and MSDSs do not apply when the written program and MSDSs are not required under § 721.72 (a) and (c), respectively. The provision of § 721.72(g) requiring placement of specific information on an MSDS does not apply when an MSDS is not required under § 721.72(c).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified § 721.80(g).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The recordkeeping requirements as specified in § 721.125 (a) through (g) and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions

of § 721.185 apply to this significant new use rule.

[55 FR 32412, Aug. 9, 1990, as amended at 57 FR 20424, May 13, 1992. Redesignated at 58 FR 29946, May 24, 1993; 58 FR 34204, June 23, 1993]

§ 721.267 N-[2-[(substituted dinitrophenyl)azo]diallylamino-4-substituted phenyl] acetamide (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as N-[2-[(substituted dinitrophenyl)azo]diallylamino-4-substituted phenyl] acetamide (PMN P-95-513) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[61 FR 63734, Dec. 2, 1996]

§ 721.275 Halogenated-N-(2-propenyl)-N-(substituted phenyl) acetamide.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substance identified generically as halogenated-N-(2-propenyl)-N-(substituted phenyl) acetamide (P-83-1085) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1) and (a)(3).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(b) *Specific requirements.* The provisions of subpart A of this part apply to